BCPharmaCare Newsletter *October 4, 2007 Edition 07-007*

ANNOUNCING THE ALZHEIMER'S DRUG THERAPY INITIATIVE

The Ministry of Health is pleased to announce the launch of the Alzheimer's Drug Therapy Initiative (ADTI) to address a clinical knowledge gap on the use of cholinesterase inhibitors for the treatment of mild to moderate Alzheimer's disease.

The goal of the ADTI is to generate and evaluate information on the safety, effectiveness, and appropriate use of these drugs in the treatment of Alzheimer's disease and to inform future government policy on coverage of these medications.

The ADTI is the result of many months of collaboration between the provincial government, the Alzheimer Society of B.C., clinical experts, researchers, practising clinicians and drug manufacturers. Nationally-renowned researchers and experts in the treatment of Alzheimer's disease have developed the research framework to provide the clinical data, including the potential impact of these drugs on care providers.

Effective **October 22, 2007**, PharmaCare will be providing coverage of the following cholinesterase inhibitors through the Special Authority process for individuals who meet the ADTI's eligibility criteria:

donepezil (Aricept®)

galantamine (Reminyl®)

rivastigmine (Exelon®)

Pharmacists play a crucial role in dementia care; your skills are integral to the success of this initiative. A dedicated page for pharmacists, including the Frequently Asked Questions provided in this newsletter, is available on the ADTI website at www.health.gov.bc.ca/pharme/adti/. The Special Authority forms designed specifically for the ADTI are also available online.

Over 25,000 British Columbians have mild to moderate Alzheimer's disease. Through the ADTI we hope to gather the additional clinical evidence needed for government to make informed decisions on the future funding of cholinesterase inhibitors for individuals affected by Alzheimer's disease.

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The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete. The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.

Important information to share with your patients

- As with all Special Authority approvals, PharmaCare coverage is subject to an individual's usual PharmaCare plan rules and deductible requirement, if any.
- No coverage is provided for cholinesterase inhibitors outside the ADTI research framework and no retroactive coverage is provided.
- Coverage is not ongoing—an individual must be reassessed and a Special Authority renewal request be submitted by their physician every 6 months.
- It is important that these drugs be taken exactly as prescribed.
- Not all patients will benefit from the medication. For those who may benefit, the effects of taking these medications are not dramatic.
- There are side effects that may need monitoring by the client's physician.
- Only the three cholinesterase inhibitors are included in the initiative. Memantine (Ebixa®) for the treatment of severe Alzheimer's disease is not included.

Questions and Answers about the ADTI

Are cholinesterase inhibitors now included in the provincial formulary?

No. The results of the evaluation of cholinesterase inhibitors will inform future government policy on coverage of cholinesterase inhibitors. As part of the ADTI, cholinesterase inhibitors are eligible for limited coverage for the period of the evaluation only, currently anticipated at three years.

Which cholinesterase inhibitors are being covered under the initiative?

Donepezil (Aricept®), galantamine (Reminyl®), and rivastigmine (Exelon®)

Is coverage going to be provided for memantine (Ebixa®)?

No, the ADTI only provides coverage of the cholinesterase inhibitors donepezil, galantamine and rivastigmine.

Are there prescription quantity limits?

If approved, cholinesterase inhibitors are covered for a monthly supply, up to 35-days for compliance packaging. If a larger quantity is requested, clients are responsible for purchasing the balance.

How long is SA approval in effect?

Special Authority approval is granted in 6-month intervals.

What is the process for coverage of cholinesterase inhibitors under the ADTI?

Coverage of cholinesterase inhibitors under the ADTI is being conducted through PharmaCare's Special Authority process.

Two separate forms have been developed for the initiative—initial coverage and renewal/switching coverage. Each form contains the assessment tools needed to determine if the patient qualifies to participate in the initiative.

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Initial coverage is granted for a 6-month period and the patient is reassessed at 6-month intervals. As long as they remain in the mild to moderate stages of Alzheimer's disease and the prescriber determines that they are responding to treatment, coverage will continue.

Pharmacists can check on IVR (interactive voice response) referring to the following DIN's, to see if a patient's coverage has been approved.

DIN	Drug
02266717	Galantamine ER 8mg
02266725	Galantamine ER 16mg
02266733	Galantamine ER 24mg
02245240	Rivastigmine 2mg/ml sol
02242115	Rivastigmine 1.5mg
02242116	Rivastigmine 3mg
02242117	Rivastigmine 4.5mg
02242118	Rivastigmine 6mg
02232043	Donepezil 5mg
02232044	Donepezil 10mg
02269457	Donepezil RDT 5mg
02269465	Donepezil RDT 10mg

Can all three cholinesterase inhibitors be tried successively?

Yes. However, there is no concurrent coverage—PharmaCare only covers one cholinesterase inhibitor at a time, with the exception of providing coverage for two medications when a patient is switching from one to another. If the patient has insufficient medication to cover the transition period, PharmaCare will approve coverage of a two-week supply.

Is a washout period necessary when switching for lack of efficacy?

The Special Authority form for renewal/switching of cholinesterase inhibitors must be submitted and approved by PharmaCare before a patient can receive coverage for a second cholinesterase inhibitor trial.

If a current cholinesterase inhibitor trial is being discontinued due to lack of efficacy, a washout period is required. It may take a washout period of 2 – 7 days before side effects are resolved.

If you have a client who is switching cholinesterase inhibitors, please dispense only a two-week supply of the current drug.

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Please refer to the **Reference Guide to Prescribing Cholinesterase Inhibitors** included in the Clinician Booklet for detailed dosage instructions (see below).

CURRENT DRUG TO BE DISCONTINUED DUE TO POOR TOLERABILITY		
STOP	*WAIT*	*START*
Donepezil	5 – 7 DAYS	galantamine or rivastigmine
Galantamine	2 DAYS	donepezil or rivastigmine
Rivastigmine	2 DAYS	galantamine or donepezil
Dose titration of new drug	As for new start	

CURRENT DRUG TO BE TAPERED OFF DUE TO LACK OF EFFICACY (mg daily)			
	Current Dose	End of Week 1	End of Week 2
Donepezil	10	5	0
	5	2.5	
	2.5	0	
Galantamine	24	16	0
	16	8	
	8	0	
Rivastigmine (>1.5mg daily, split into twice daily dosing if possible)	12	6	0
	9	4.5	
	6	3	
	3	1.5	

NEW DRUG TO BE ADDED WHILE CURRENT DRUG TAPERED (mg daily)				
	Current Dose	End of Week 1	End of Week 2	Maximum Dose**
Donepezil OR	-	5 (2.5 if frail)	5	10
Galantamine OR	-	8	16	24
Rivastigmine	-	1.5 to 3 twice daily	6 to 12	12 (6 twice daily)

** Titrate to maximum dose if tolerated and clinically indicated.

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What warnings/precautions are considered by the prescriber when determining whether an individual should be treated with a cholinesterase inhibitor?

The conditions to consider when making this determination are:

- peptic ulcer disease
- hepatic or renal disease
- significant bradycardia or AV block
- significant bronchospastic disease
- obstructive urinary disease
- epilepsy
- history of seizures or drug interactions.

If a Special Authority form is submitted before the initiative is launched, what will happen to it?

ADTI Special Authority forms received before the launch date will be held and processed after the official launch date.

What happens to patients who are prescribed a cholinesterase inhibitor but Special Authority approval is denied because they don't meet ADTI criteria?

Individuals not eligible to participate are responsible for their full prescription cost.

What happens if the patient was prescribed a cholinesterase inhibitor before the ADTI program started and they come in for a refill?

You should advise your client to visit their physician for an assessment to determine if they are eligible to participate in the ADTI. If they are, it is important to let them know that coverage is effective from the date PharmaCare's Special Authority approval is granted and is not retroactive.

PharmaCare coverage under the ADTI is subject to the patient's plan, annual deductible and family maximum.

Will patients be eligible for coverage of cholinesterase inhibitors while travelling?

Special Authority may consider coverage of cholinesterase inhibitors for patients required to travel. For consideration of such requests, please contact the Special Authority Unit directly by fax to 1 800 609-4884.

Are nurse practitioners eligible to prescribe cholinesterase inhibitors?

Yes, if it is within their scope of practice as determined by the College of Registered Nurses of B.C.

Will Special Authority coverage of cholinesterase inhibitors be granted to individuals who are currently covered by the Department of Veterans Affairs?

No.